Statement of Chairman Tom Davis
Committee on Government Reform Hearing
"The Nation's Flu Shot Shortage: Where are We Today and How Prepared are We for Tomorrow?"
November 17, 2004

Good afternoon, a quorum being present, the Committee on Government Reform will come to order. I want to welcome everyone to today's hearing, the Committee's second oversight hearing in six weeks on this years' U.S. influenza vaccine supply.

As most are now aware, on October 5, 2004, the Medicines and Healthcare Products Regulatory Agency, the United Kingdom's version of the U.S. Food and Drug Administration, suspended Chiron Corporation's manufacturer's license for a period of three months. Chiron planned on delivering 46-48 million doses of flu vaccine, almost half of the U.S. supply.

This Committee's investigation into the issues surrounding the flu vaccine shortage began at a flu pandemic hearing in February of this year. The Committee informed U.S. health officials of its concern that Chiron did not have a manufacturing plant located within the U.S. Should a flu pandemic occur, it was theorized that the U.K. could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply.

At an emergency October 8, 2004 hearing, the Committee discussed contributing factors to the flu vaccine shortage, how the government and vaccine manufacturers were responding to and managing the crisis, and what steps would be taken to prepare for next year's flu season.

As a result of testimony at these two hearings, Ranking Member Waxman and I sent a letter to FDA requesting documents that would indicate whether FDA knew about the problems at the Chiron facility and whether FDA responded adequately.

As part of the Committee's investigation, I led a CODEL to London last week to meet with top ranking officials from MHRA and Chiron. The Committee also conducted an extensive meeting with FDA officials in Washington to discuss FDA documents and the Committee's findings from

meetings held in London. These meetings were extremely productive and provided the Committee with a timeline of events leading up to October 5, the standard protocols used by MHRA and FDA, and the steps all parties involved are taking to prevent future flu vaccine shortages.

The FDA documents and investigative meetings held by the Committee confirm several key facts. First and foremost, FDA was unaware prior to October 5, 2004 that MHRA would suspend Chiron's manufacturing license.

On August 25, 2004, Chiron contacted the FDA to alert the Agency there may be a delay in its vaccine shipment, as contamination was located in some lots of Chiron's flu vaccine. All documents and meetings confirm that FDA followed routine protocol in responding to Chiron's initial contact with the FDA and continued to follow protocol with each step the Agency took after August 25th.

Chiron also notified FDA that it had conducted an internal failure investigation to discover how the contamination occurred. It is standard protocol for FDA to have a manufacturer's failure investigative report in hand when conducting an inspection. The FDA uses the report in determining cause, and the report serves as a roadmap for the inspection. Chiron informed FDA that it would receive the internal report the week of October 4, 2004. FDA has informed the Committee that it believed this was a reasonable timeframe. During this time, FDA was in constant communication with officials from Chiron and immediately alerted the Centers for Disease Control and Prevention about the delay in Chiron's shipment.

Unfortunately, the internal report was not provided to FDA until after Chiron's license suspension. The MHRA, however, was provided with Chiron's findings on September 24, 2004. As a result, MHRA concluded its final investigative visit to Chiron on September 30, 2004. The FDA has since reviewed the report and instructed Committee staff that had the Agency received the draft report sooner, the Chiron facility would have been reinspected, whether or not MHRA suspended Chiron's manufacturing license.

FDA, MHRA, and Chiron all agree that Chiron's license suspension resulted from systemic problems within Chiron's Liverpool facility, based on a lack of manufacturing oversight and execution. In addition, all parties agree that

prior inspections conducted by both FDA and MHRA at the Chiron facility did not foreshadow the license suspension. While some issues at the facility continued from 2003 until September of 2004, Chiron's license suspension was not based on contamination in flu vaccine lots or other issues addressed in previous inspections. It would be inappropriate to imply that problems at the Chiron facility in 2003 recurred in 2004 and contributed to the closure of the facility.

Questions have been asked as to why FDA was kept in the dark regarding Chiron's license suspension until October 5th. Pursuant to the U.K's Medicines Act, MHRA is prohibited from sharing commercial information without the consent of the manufacturer involved. FDA, MHRA, and Chiron all informed Committee staff that it is widely accepted and understood that the two Agencies do not discuss their own actions with regard to companies over which they each have jurisdiction. In addition, it would be standard procedure for Chiron not to discuss its interaction with FDA or MHRA with the other Agency. Since October 5th, Chiron has permitted FDA and MHRA to communicate on all issues.

This investigation has been conducted in a bipartisan manner. Politics has no place in the public health arena. I hope this spirit of cooperation is not threatened today by those who choose to ignore standard FDA protocol, accepted by vaccine manufacturers worldwide, and place the sole blame on for the U.S. flu vaccine shortage on a single Agency, rather than taking an objective look at all the facts presented during the Committee's investigation. If protocols need to be tweaked, then let's talk about tweaking them.

After all, should FDA be held accountable for decisions made by Chiron without its knowledge or for actions taken by MHRA that were legally protected by law of the U.K.? If the Committee spends too much time placing blame and pointing fingers, we will be unable to look to the future to ensure the U.S. has an adequate flu vaccine supply. Let's let experience be our teacher.

My main goals in this investigation are to understand the lessons learned from the events leading up to and occurring since October 5, 2004, and most importantly, to work vigilantly with U.S. health officials and private industry to ensure that a similar situation does not occur in the future.

Based on my meetings with FDA, MHRA, and Chiron, I am optimistic that Chiron will be able to produce vaccine for next year's flu season. The license suspension did not prohibit Chiron from procuring its start up materials for next year. As of today, Chiron has contracted and paid for its egg supply for the 2005-2006 flu season. MHRA is extremely pleased with the remediation plan Chiron submitted and a follow up inspection will be conducted in late December to evaluate Chiron's progress.

It is important to recognize there is a need to expand the current number of FDA approved flu vaccine manufacturers and to bring these manufacturers into the U.S. I will work on legislation designed to provide incentives to flu vaccine manufacturers, in hopes that we can stimulate the vaccine market domestically.

Since our October 8, 2004 hearing, both Aventis Pasteur and Medimmune have been able to produce additional doses of flu vaccine. FDA has also identified and negotiated for approximately 5 million doses of flu vaccine from foreign manufacturers. Additionally, the nation has a supply of enough antiviral medicines to treat about 40 million people. These antiviral drugs can be used to prevent or treat the flu if symptoms are identified early.

Our witnesses today will discuss how U.S. health officials are procuring and adequately distributing the flu vaccine to the high-risk population and preparing for next year's flu season and what incentives can be provided to manufacturers to ensure a stable annual flu vaccine supply.

In addition, I am pleased that Howard Pien, President of Chiron Corporation is present to speak publicly for the first time since October 5, 2004. I know we are anxious to hear his testimony as to Chiron's remediation plan and how Chiron is moving forward in preparation for next year's flu season.

We have an excellent roster of witnesses today and I would like to thank all of them for appearing before the Committee and I look forward to their testimony.